

REMARKS/ARGUMENTS

Claims 1-7, 9-10, and 21-31 are now pending. Applicants have amended claim 1 to recite the step of refrigeration; however, Applicants reserve the right to later claim subject matter of the present invention that does not recite refrigeration. Support for this amendment to claim 1 can be found throughout the specification and claims, e.g., original claim 8. Applicants have cancelled claims 8 and 11-20 without prejudice, reserving the right to file a continuation/divisional application on the subject matter of these claims. Applicants have added new claims 21-31. Support for such new claims can be found throughout the specification and claims, e.g., original claim 10 and page 4, line 15. Accordingly, no issues of new matter are believed to have been raised by the above amendments.

Applicants earnestly believe that in view of the amendments and remarks herein, all outstanding rejections have been overcome, and accordingly this application is in condition for allowance.

**I. Rejection Under 35 U.S.C. § 103 Over Mehta et al. in View
of Klaus et al.**

Claims 1-10 were rejected as being unpatentable over Mehta et al., (US Patent No. 6,200,597), in view of Klaus et al., (US Patent No. 5,958, 956). See Pages 3-5 of the Office Action. Applicants respectfully traverse the rejection.

The Office Action states that “[Mehta] teaches a formula and use of carotenoids wherein the carotenoids are referring to retinoids, proretinoids, phenyl analog of retinoic acid and analogs thereof. . . . It further teaches a method of administering said carotenoids composition by topical administration via reconstitution method.” See Page 3 of the Office Action. The Office Action then continues stating “Applicants claims differ in that they require a retinoid derivative having a specific formula I as shown in the instant claim 1 [Klaus et al.] teaches the compounds of Formula I as selective ligands of retinoic acid receptors It also teaches that the topical formulations of said active substances . . .” See Pages 3-4 of the Office Action.

While Klaus et al. does disclose compounds of formula I and the topical use of such compounds “in the form of ointments, tinctures, creams, solutions, lotions, sprays, suspensions, and the like (See col. 4, lines 8-15 of Klaus, et al.),” it does not disclose the instability of such compounds in topical formulations, as discovered by the Applicants. As discussed in the background of the invention of the present application, the instability of these compounds inhibits the ability to market such compounds in a shelf-stable, topical formulation. As many retinoids, such a tretinoin and retinol, are sold in shelf-stable, topical formulations (see Retin-A® Cream, containing retinoic acid, attached hereto as Exhibit A and Neutrogena Healthy Skin® Anti-Wrinkle Cream, containing retinol, attached hereto as Exhibit B), one of ordinary skill in the art would not be led to administer the retinoids of formula I using the currently claimed method as such formulation difficulties are not disclosed, nor suggested, by Klaus, et al.

Assuming arguendo that one would look to alternative methods of topically administering the compounds of Klaus, et al., one of ordinary skill in the art would not look to Mehta et al. Mehta, et al. teaches reducing the toxicity of compositions of carotenoids. See the Summary of the Invention of Mehta et al., col. 2, lines 59-60. As discussed in Mehta et al. on col. 2, line 64-65, a “preferred example is all-trans retinoic acid,” which is a retinoid that is currently formulated in a shelf-stable, topical formulation (see Retin-A® Cream attached hereto as Exhibit A). Thus, one of ordinary skill in the art would not look to Mehta, et al. for methods of administering retinoids that are not so stable. Therefore, it would not have been obvious at the time of the invention to look at Mehta to formulate compounds of Formula I.

Additionally, as discussed above, Claim 1 of the present invention now recites the step of "refrigerating said formulation." Such a step is not taught, nor suggested, by Mehta et al. nor Klaus, et al.

Accordingly, Applicants respectfully request that this rejection under 35 USC 103 be withdrawn.

In view of the foregoing amendments and remarks, Applicants submit that the application is in condition for allowance. Accordingly, Applicants respectfully request allowance of the pending claims.

Respectfully submitted,

A handwritten signature in black ink, appearing to read 'W. McGowan', is written over a horizontal line.

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